



INTRATYMPANIC STEROID INJECTION IN THE TREATMENT OF OTITIS MEDIA WITH EFFUSION

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ABSTRACT

Study Background: Otitis Media with effusion is a common problem, especially in children, resulting from the poor function of the Eustachian tube. It is associated with conductive hearing loss and tinnitus, and it is the most common cause of hearing deficiencies in children, which negatively affects their linguistic and social development.

Objective: To determine the effectiveness of Intratympanic steroid injection as a new therapeutic approach for Otitis Media with effusion. **Materials and Methods:** A prospective, observational study, coupled with a control group. The number of patients reviewed was 30 (60 ears), of which 56 ears met the criteria for inclusion and exclusion, as 4 ears were intact. They were divided into two groups according to a random distribution schedule: the first group (A) received budesonide injections into the tympanum, and the second group (B) had ventilation tubes installed. Along with the required surgical procedure for each patient. The first group received injections four consecutive times over four weeks. Patients were evaluated based on the results of audiometry, impedance, and complications after more than four months. **Results:** The degree of hearing improvement was better in the group that received the injections (P-value = 0.002), and the postoperative complications were lower, but the possibility of recurrence was higher (P-value = 0.0001). **Conclusions:** Intratympanic Steroid injection are safe and rapid intervention that benefits the treatment of otitis media with effusion, but there is a possibility of recurrence.

KEYWORDS: Otitis Media with effusion, Intratympanic steroid injection, Budesonide.

INTRODUCTION

Serous otitis media (OME) is already a common problem among children and can negatively affect their linguistic and social development. The treatments available vary and depend on several factors, including the severity of the condition and the accompanying symptoms.^[1,2]

Vigilant monitoring with waiting, as recommended by the American Academy of Pediatrics (AAP), may be appropriate for some cases, especially if the symptoms are mild and do not significantly affect the child. However, in cases of children who are at a sensitive stage of language acquisition and learning, temporary medical treatment may be preferred to avoid any delays that may affect their development.^[3]

Steroids, such as intra-tympanic injections, are used to reduce inflammation and improve hearing by delivering the drug directly to the middle ear. This approach can be effective in reducing inflammatory effectiveness and preventing complications.^[5]

OBJECTIVES

- Determine the effectiveness of intra-tympanic steroid injections as a new treatment for OME.
- Evaluate the improvement in hearing and complications after treatment to determine the best treatment options for affected children.

MATERIALS AND METHODS

Study design: A prospective, observational study, coupled with a control group.

Study Place and duration: The study was conducted in the Department of otorhinolaryngology at Tishreen University Hospital in Latakia for a period of one year after receiving informed consent.

Sample Study

- **Inclusion criteria**

Patients presenting to the Department of otolaryngology and surgery at Tishreen University Hospital in Latakia, includes children between 3 and 13 years old, that is an

age group sensitive to the effects of OME on hearing and language development, and complaining of hearing loss or a sense of ear fullness during a year from March 2022 to March 2023.

• Exclusion criteria

1. Immunocompromised patients, chronic diseases, oncological and Anamnesis were subjected to radiotherapy of tumors in the head and neck area.
2. active respiratory diseases and active upper respiratory infections in the last week.
3. Mental problems.
4. Craniofacial malformations and congenital syndromes (down, cleft palate sail, fibrocystic disease).
5. Previous ear, nose and throat surgeries.
6. Morphological changes in the structure of the tympanic membrane and anomalies of the middle ear.
7. Allergy to steroids (budesonide).
8. Patients who are unwilling to participate or who have not completed the study.

The patient sample was 30 patients (56 ear)

Methodology

1. Pre-operative

- The participating patients were interviewed and informed consent was obtained from them or from their relatives.
- Taking the detailed medical, surgical, family, and pharmacological history and about the current complaint.
- A clinical examination of patients was conducted : an ear examination by a pneumatic otoscope (Siegel) with an assessment of tympanic membrane motion, a tuning fork test : Rene, Weber. The pharynx, nose and mouth were also examined.
- Endoscopy of the nasal cavity to investigate the presence of nasal problems and adenoid hypertrophy, and when endoscopy was not possible, a simple radiograph was requested to assess the size of the adenoids.
- Auditory impedance test: to evaluate the kinetics of the tympanic membrane.
- Electroacoustic Audiometer: to renew the type, destination and degree of hearing deficiency.
- Determined the need for surgical intervention
- Anesthesia consultation was made for all patients.
- Patients sample was divided randomly into two groups : group (A) the first ear was injected with budesonide in the tympanic cavity, group (b) the econd ear was fitted with a ventilation tube.

±±We made a tympanotomy and the secretions were suctioned from the ear, we injected budesonide in the

tympanic cavity of one ear, and a ventilation tube was installed on the other ear.

Patients didn't receive any systemic steroids, antibiotics, antihistamines, anticongestants, or antileukotrienes.

3. Postoperative

Injection was repeated in the same ear once a week for 4 weeks with assessment of early and late complications.

In the follow up period we have assessed

1. Size and type of infusion.
2. Immediate adverse effects (pain, bleeding, itching, ear fullness sensation, tinnitus, hearing improvement, nausea and vomiting), late adverse effect (tympanic membrane perforation, infection, discharge, tympanic membrane sclerosis).

After 4 months we have repeated the tympanometry and PTA.

Statistical analysis

- Data were entered, checked, and analyzed using BM SPSS statistics(v25).
- X2 (chi-squared) was used for difference between qualitative variables.
- T-student was used for difference between quantitative variables

RESULTS

- Our study was conducted on 30 patients(56 ears), their ages ranged between 3 and 13 with a mean of 7.5 ± 3.1 years old and we observed that the majority of patients were in the age group between 3 and 6 (46,7%). [Table 1]

Table 1: Patients' distribution according to age and sex.

		Number	%
Sex	Male	21	70%
	Female	9	30%
Age groups	3-6	14	46,7%
	6-9	9	30%
	>9	7	23,3%

- 26 patients had bilateral disease(86.7%) while 4 patients had unilateral disease.

All patients complained of hearing loss (100%), 9 patients had aural fullness, 3 patients had tinnitus and two patients complained of otalgia. [figure 1]

Preoperative Tympanometry was type B in 33 ears(58.9%), and type C in 23 ears(41.1%).[figure 2]

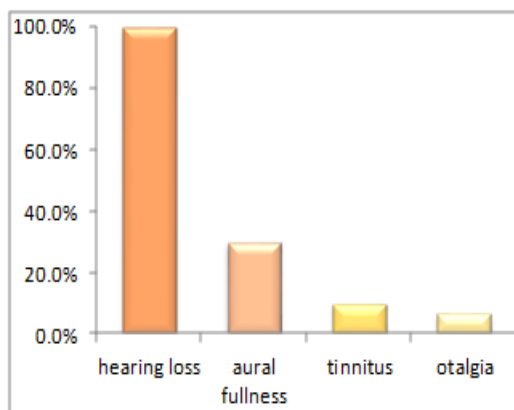


Figure 1: symptoms rate in patients.

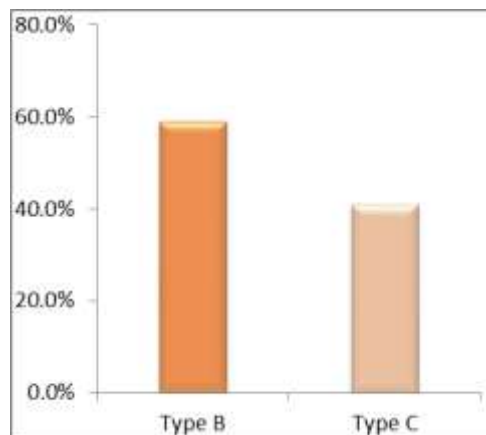


Figure 2: preoperative Tympanometry type in patients.

- No statistically significant differences were found according to Preoperative pure tune audiometer between group A and group B. [table 2][figure 3]

- We found significant differences between the two groups according to hearing levels on PTA at all studied frequencies, hence the mean values were lower in steroid injected group.

Table 2: Preoperative Pure Tune Audiometer.

Frequencies	Group A (Mean HLs)	Group B (Mean HLs)	P- value
500	38.39+ 4.6	37.22+ 2.3	0.5
1000	37.62 +_ 4.8	36.7+_ 3.4	0.8
2000	34.28 +_ 5.32	35.27+_ 5.9	0.2
4000	33.71 +_ 4.2	33.88+_ 4.1	0.1

Table 4: Post Operative PTA.

Frequencies	Group A	Group B	P- Value
500	23.32 +_ 3.9	30.22+_ 2.3	0.002
1000	17.77+_ 4.1	27.71 +_ 3.4	0.0001
2000	13.11 +_ 5.32	25.27 +_ 5.9	0.0001
4000	15.21 +_ 4.2	23.88 +_ 4.1	0.004

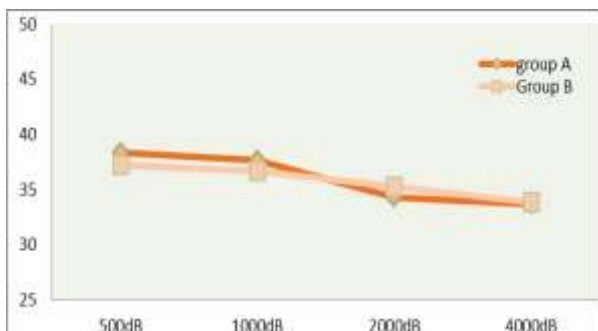


Figure 3: Preoperative Pure Tune Audiometer.

- We found significant differences between groups according to postoperative tympanometry results, hence 63.3% Of steroid group tympanometry became type A, versus 42,3% in the other group. (p-value= 0,002).

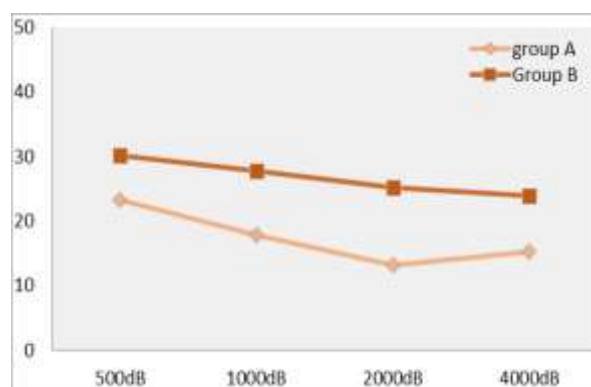


Figure 5: Post operative PTA.

- We found significant differences between group A and B according to postoperative complications, tympanic membrane perforations were found just in group B, tympanic membrane sclerosis incidence was higher in group B, no differences were found according to discharge from ear referring that local steroid doesn't increase infections rate as systemic steroid. [table A]

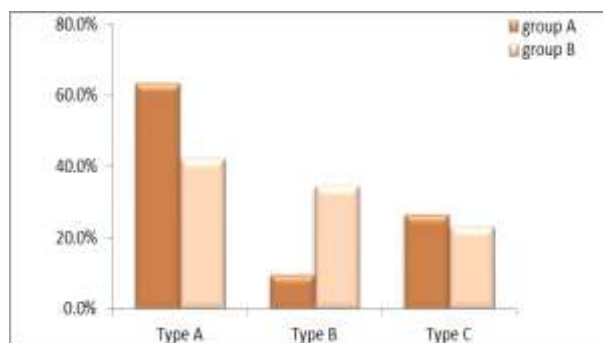
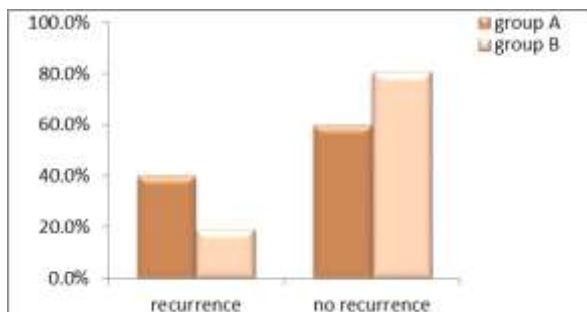


Figure 4: Postoperative Tympanometry Type In Study Groups.

Table 5: postoperative complications.

Complications	Group A	Group B	P-value
TM perforation	(0 %) 0	(11.5 %) 3	0.001
TM sclerosis	(30 %) 9	(42.3 %) 11	0.02
No complication	(70 %) 21	(46.2 %) 12	0.0001

- We found significant differences between groups according to recurrence rate which was higher in group A. [Figure 6]

**Figure 6: recurrence rate in the follow-up period.**

DISCUSSION

- Otitis Media with effusion is a common problem, especially in children, resulting from the poor function of the Eustachian tube. It is associated with conductive hearing loss and tinnitus, and it is the most common cause of hearing deficiencies in children, which negatively affects their linguistic and social development.
- Steroids have become popular in the treatment of OME, especially in the early stage of the disease. This is attributed to its anti-inflammatory properties and its ability to reduce mucosal production and improve eustachian tube function.
- In our study we found that intratympanic steroid injections, especially budesonide (due to its rapid and long-acting effect on the mucus membrane) are safe, quick and simple without any complications, and are useful in delivering the medication directly and decreasing the adverse effects of systemic steroids.
- We found that steroid injections are superior to ventilation tube insertion in improving hearing and reducing complications resulting from tube placement and the need for general anesthesia and hospitalization, but the possibility of recurrence remains higher in the case of injections.
- In a study conducted by Hembrom, R. et Al^[6], they compared between intratympanic steroid injections and the conventional medical treatment in resistant cases of otitis media with effusion and they found that dexamethasone injection is superior in improvement of hearing and it's a safe and effective treatment in these resistant cases.
- Yang, F., et Al in their study^[7] divided their patients randomly into 3 groups, each group had an intratympanic injection of budesonide 0.5 mg/ml (group1), dexamethasone 0.5 mg/ml (group 2), and normal saline 0.9% (group3). Group 1 &2 showed

more symptomatic improvement than group 3 (p value =0.05), moreover budesonide group showed more relief in their aural fullness sensation compared with dexta & NS groups. No adverse effects were found in the follow-up period.

- Saleh, A. S. M et Al^[8] compared between Grommet Tube Insertion versus Myringotomy with Intratympanic Steroid Injection in Treatment of Otitis Media with Effusion, no differences were found according to persistent of discharge and tympanic membrane sclerosis, however they found significant differences according to recurrence rates which were higher in steroid injection group.

CONCLUSION

- Intratympanic Steroid injection are safe and rapid intervention that benefits the treatment of otitis media with effusion, but there is a possibility of recurrence.
- It's preferable to insert a ventilation tube in addition to steroid drops to obtain the best results and decrease any complications.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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